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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,607	10/03/2001	Valerie L. Gerlach	15966-675 CIP 2 (Cura-175	2700

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EXAMINER	
MCKELVEY, TERRY ALAN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,607	GERLACH ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 29, 32, 35, 44-47, 68, and 71, drawn to isolated polypeptide, pharmaceutical composition, kit, and use of a therapeutic in the manufacture of a medicament, classified in class 530, subclass 350 and class 514, subclass 12.

II. Claims 5-14, 30, 33, 36, 48-57, 69, and 72, drawn to isolated nucleic acid molecule, vector, cell comprising vector, pharmaceutical composition, kit, and use of a therapeutic in the manufacture of a medicament, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 325, 243, 419, and class 514, subclass 44.

III. Claims 15-17, 31, 34, 37, 58, 70, and 73, drawn to antibody, pharmaceutical composition, and kit, classified in class 530, subclass 387.1 and class 424, subclass 130.1+.

IV. Claims 18 and 59, drawn to method for determining amount of polypeptide in sample, classified in class 435, subclass 7.1.

V. Claims 19 and 60, drawn to method for determining amount of nucleic acid molecule in sample, classified in class 435, subclass 6.

VI. Claims 20 and 61, drawn to method of identifying an agent that binds to the polypeptide, classified in class 435, subclass 7.8.

VII. Claims 21 and 62, drawn to method for identifying a potential therapeutic, classified in class 435, subclass 29.

VIII. Claims 22 and 63, drawn to method for modulating the activity of the polypeptide, classified in class 435, subclass 375.

IX. Claims 23-24, 42, 64-65, 78, drawn to method of treating or preventing pathology comprising administering polypeptide, classified in class 514, subclass 12.

X. Claims 25-26 and 66, drawn to method of treating or preventing pathology comprising administering a NOVX nucleic acid, classified in class 514, subclass 44.

XI. Claims 27-28, 43, 67, and 79, drawn to method of treating or preventing pathology comprising administering a NOVX antibody, classified in class 424, subclass 130.1.

XII. Claims 38-39 and 74-75, drawn to method for screening for a modulator of activity, classified in class 800, subclass 3.

XIII. Claims 40 and 76, drawn to method for determining the presence or predisposition to a disease associated with altered levels of polypeptide, classified in class 435, subclass 7.1.

XIV. Claims 41 and 77, drawn to method for determining the presence or predisposition to a disease associated with altered levels of nucleic acid molecule, classified in class 435, subclass 6.

Groups I-XIV are comprised of multiple inventions which are the products or methods drawn to different, distinct, and independent sequences, drawn to different proteins and genes, which do not render obvious each other and thus are independent and distinct. Applicants must also elect a single invention which is the product or method drawn to one specific sequence to which the claims will be restricted. This is not an election of

species because the sequences are independent and distinct inventions and thus the products or methods drawn to different independent and distinct sequences are independent and distinct inventions from each other. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application. Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to distinct types of products and methods, followed by an election of a single invention drawn to one sequence within the elected multi-invention group was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention drawn to each separate sequence which would require a communication over ten times as long.

The inventions are distinct and/or independent, each from the other because of the following reasons:

The isolated polypeptides, etc of Group I, isolated nucleic acid molecules, etc, of Group II, and the antibodies, etc of Group III, are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

Inventions of Groups IV-XIV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups IV-XIV comprise steps which are not required for or present in the methods of the other groups. The end result of the methods are different from each other. Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group I and Groups VI, IX, and XIV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group I can be used in a materially different process, as evidenced by the distinct methods of Groups VI, IX, and XIV.

Inventions of Group II and Groups V, VII-VIII, X, and XII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group II can be used in a materially different process, as evidenced by the distinct methods of Groups V, VII-VIII, X, and XII.

Inventions of Group III and Groups IV, XI, and XIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case,

the product of Group III can be used in a materially different process, as evidenced by the distinct methods of Groups IV, XI, and XIII.

Except for the specific relationships described above, the inventions of the products of Groups I-III and the methods of Groups IV-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products of Groups I-III are not required to be used in or made by the methods of Groups IV-XIV.

Because these inventions are distinct and/or independent for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on

Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

October 1, 2003